



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,841	08/31/2005	Alexander Gaiger	210121.49402USPC	9134
500	7590	12/10/2008	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			CANELLA, KAREN A	
701 FIFTH AVE			ART UNIT	PAPER NUMBER
SUITE 5400			1643	
SEATTLE, WA 98104				

  

MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/501,841	GAIGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 17-53 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 17-53 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>6/11/07</u> .	6) <input type="checkbox"/> Other: ____ .

## **DETAILED ACTION**

Claims 1-16 have been canceled. Claims 17-53 are pending and under consideration.

### ***Priority***

Acknowledgment is made of PCT/US03/02353 claim for benefit of an earlier effective filing date through U.S. 10/057,475, filed January 22, 2002

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-33, 39-51 are rejected under 35 U.S.C. § 101 because they are not presented in the format of a proper process claim. See MPEP 2173.05(q).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-33 and 39-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claims 17-33 drawn to the use of an antibody are vague and indefinite. The claims are drawn to a method of using an antibody, but fails to set forth any active, positive steps that define the claimed method. See MPEP 2173.05(q).

(B) The recitation of “administration” in claim 33 lacks antecedent basis in claims 17 and 18.

(C) Claims 39 and 40 are vague and indefinite because it is unclear what is being set forth within SEQ ID NO:4 and 56, respectively.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

In the instant case, the contemplation of a nucleic acid encoding a monoclonal antibody which specifically binds to SEQ ID NO:4 or SEQ ID NO:56 is paramount to a contemplation of what the nucleic acid does rather than what it is. One of skill in the art would reasonably conclude that applicant was not in possession of the invention at the time of filing.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17, 19, 21-34, 36-39, 42-51 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Kindsvogel (WO 2002066516).

Claim 17 is drawn to the use of an effective amount of an isolated monoclonal antibody that specifically binds to a polypeptide comprising SEQ ID NO:4 in the manufacture of a medicament for treatment of a hematological malignancy in a mammalian subject. Claim 19 embodies claim 17 wherein the malignancy is associated with over expression of BCMA. Claims 21-25 embody claim 17 wherein the antibody is humanized, chimeric, a Fab fragment, a Fv fragment, and a scFv, respectively. Claim 26 specifies that the antibody of claim 17 further comprises a therapeutic moiety. Claim 27 specifies that the therapeutic moiety is a radionuclide and claim 28 requires that the radionuclide be selected from a group including  $^{131}\text{I}$ . Claim 29 embodies the use of claim 17 wherein the hematological malignancy is selected from a group including B cell lymphomas and B cell leukemias. Claim 30 embodies the use of claim 17 wherein the malignancy is CLL. Claim 32 embodies the use of claim 17 wherein the subject is human. Claim 33 embodies the use of claim 17, wherein the administration is intravenous.

Claims 34-38 are drawn to a method comprising the steps of (a)contacting a biological sample from a patient with a monoclonal antibody that specifically binds to SEQ ID NO:4 and detecting the complex formed between the monoclonal antibody and SEQ ID NO:4.

Claim 39 is drawn to an isolated monoclonal antibody that specifically binds SEQ ID NO:4. Claims 43-47 embody the isolated antibody of claim 39 wherein said antibody is humanized, chimeric, a Fab fragment, a Fv fragment and a scFv, respectively. Claim 48 embodies the antibody of claim 39 further comprising a reporter group. Claim 49 embodies the antibody of claim 39 further comprising a therapeutic moiety. Claim 50 specifies that the therapeutic moiety is a radionuclide. Claim 51 further specifies that the radionuclide is selected from a group including 131I. Claim 52 is drawn to a kit comprising a monoclonal antibody that specifically binds SEQ ID NO:4 and instructions for use.

Claim 42 is drawn to a pharmaceutical composition comprising the monoclonal antibody of claim 39 and a pharmaceutically acceptable carrier.

Kindsvogel discloses a monoclonal antibodies that bind to BCMA (page 23, line 27 to page 24, line 33 and page 53 Table I) and bi-specific antibody that binds to BCMA (pages 15-16 under the heading of “Production of anti-BCMA-TACI Antibodies”), wherein the sequence of BCMA (Sequence Identifier 2) is identical to the instant SEQ ID NO:4:

WO200266516-A2.

XX

PD 29-AUG-2002.

XX

PF 06-FEB-2002; 2002WO-US003500.

XX

PR 20-FEB-2001; 2001US-0270274P.

PR 12-APR-2001; 2001US-0283447P.

XX

PA (ZYMO ) ZYMOGENETICS INC.

XX

PI Kindsvogel W;

XX

DR WPI; 2002-723183/78.

DR N-PSDB; AAD46410.

DR PC:NCBI; gi399104.

Art Unit: 1643

DR PC:SWISSPROT; Q02223.

XX

PT B-cell maturation antigen and transmembrane activator and calcium-modulator and cyclophilin ligand-interactor, useful for treating disorders e.g. inflammation or lymphoma.

XX

PS Disclosure; Page 63; 67pp; English.

XX

CC The invention relates to the manufacture of a composition for inhibiting the proliferation of tumour cells. The method involves using an antibody component that binds both the B-cell maturation antigen (BCMA) and the transmembrane activator and calcium-modulator and cyclophilin ligand-interactor (TACI). BCMA and TACI binding antibody compositions are useful for inhibiting proliferation of tumour cells, particularly inhibiting ZTNF4 activity in a mammal associated with increased endogenous antibody production or a disorder consisting of neoplasm, chronic lymphocytic leukaemia, multiple myeloma, non-Hodgkin's lymphoma, post-transplantation lymphoproliferative disease or light chain gammopathy or inflammation e.g. asthma. The invention is also useful in gene therapy. The present is human BCMA protein

CC

SQ Sequence 184 AA;

Query Match 100.0%; Score 964; DB 5; Length 184;  
Best Local Similarity 100.0%; Pred. No. 2.5e-94;  
Matches 184; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 MLQMAGQCSQNEYFDSLLHACIPCQLRCSSNTPPLTCQRYCNASVTNSVKGTNAILWTCL 60  
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db 1 MLQMAGQCSQNEYFDSLLHACIPCQLRCSSNTPPLTCQRYCNASVTNSVKGTNAILWTCL 60

Qy 61 GLSLIISLAVFVLMFLLRKISSEPLKDEFKNTGSGLGMANIDLEKSRTGDEIILPRGLE 120  
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db 61 GLSLIISLAVFVLMFLLRKISSEPLKDEFKNTGSGLGMANIDLEKSRTGDEIILPRGLE 120

Qy 121 YTVEECTCEDCIKSXPVDSDFCFPLPAMEEGATILVTTKTNDYCKSLPAALSATEIEKS 180  
||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db 121 YTVEECTCEDCIKSXPVDSDFCFPLPAMEEGATILVTTKTNDYCKSLPAALSATEIEKS 180

Qy 181 ISAR 184

Db 181 ISAR 184

Kindsvogel discloses that the bi-specific antibody is useful in the treatment of B lymphomas and chronic lymphocytic leukemia (page 6, lines 13-19) which is the same as that disclosed in the instant specification (page 24, section [181]) and originally filed claims (claim 16). Kindsvogel discloses that the bi-specific antibody further comprises a therapeutic moiety (page 37, lines 14-37, page 38, lines 1-2 and page 49, lines 3-4) which includes <sup>90</sup>Y, <sup>123</sup>I, <sup>131</sup>I, and <sup>186</sup>Re (page 37, lines 6-14). Kindsvogel discloses that the antibodies encompass humanized, chimeric Fab or scFv fragments (page 4, lines 17-22). Kinsvogel discloses pharmaceutical compositions comprising the antibodies (page 43, lines 13-35) and the administered via an intravenous route (page 42, line 35). Kinsvogel discloses kits comprising the anti-BCMA-TACI antibody or fragments with a "means for conveying to the user" that the antibody or fragments are used to detect BCMA or TACI proteins (page 32, lines 1-12) which meets the limitation of claim 52.

Kindsvogel discloses a method wherein a biopsy sample is contacted with the antibodies in order to detect the relative abundance and/or distribution of BCMA which meets the limitation of claims 34 and 36-38 . It is noted that the recitation of "method for the detection of a hematological malignancy in a patient" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is further noted that the phrases "thereby detecting cancer in said patient", "wherein the hematological malignancy is selected from the group consisting of B cell lymphoma, B cell leukemia and multiple myeloma, and combinations thereof", "wherein the hematological malignancy is chronic lymphocytic leukemia", and "wherein the hematological malignancy is multiple myeloma" , are not given patentable weight when comparing the claims to the prior art

because these phrases refer to the abstract conclusion, rather than an active method step or concrete product.

Given that the method of the prior art comprises the same method steps as claimed in the instant invention, the claimed method is anticipated because the method will inherently be a method for diagnosing a hematological malignancy. See *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993)..

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kinsvogel (WO 02/066516).

Claim 31 embodies the use of claim 17 wherein the hematological malignancy is multiple myeloma.

Kinsvogel teaches that human multiple myeloma cell lines express high levels of BCMA as determined by anti-BCMA antibody binding, but relatively low levels of TACI (Page 54,

Table II). Kinsvogel concludes that BCMA provide a suitable marker for targeting multiple myeloma (page 53, lines 24-25).

It would have been prima facie obvious at the time that the claimed invention was made to administer anti-BCMA monoclonal antibodies conjugated to a therapeutic moiety for the treatment of patients having multiple myeloma. One of skill in the art would have been motivated to do so by the teachings of Kinsvogel on the high level of BCMA expressed on multiple myeloma cells and the suggestion by Kinsvogel that the expression of BCMA can be used to target multiple myeloma.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kinsvogel (WO 02/066516).

Claim 41 is drawn to a nucleic acid encoding the monoclonal antibody of claim 39. Kinsvogel discloses the 255.4 antibody which binds to BCMA (page 53, Table II). Kinsvogel discloses that the antibodies that bind to BCMA include humanized, chimeric and scFv antibodies (page 4, lines 17-22). Kinsvogel does not specifically disclose the nucleic acid sequence encoding said antibodies.

It would have been prima facie obvious at the time that the claimed invention was made to provide the nucleic acid sequence encoding said antibodies. One of skill in the art would have been motivated to do so in order to attain the humanized, chimeric and scFv antibodies taught by Kinsvogel because humanized, chimeric and scFv antibodies are synthetic antibodies, the proteins of which are not found in nature. Therefore said antibodies must be recombinant expressed and the nucleic acid is required.

Claim 40 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brauner-Osborne et al (Biochimica et Biophysica Acta, 2001, Vol. 1518, pp. 237-248) in view of Campbell (Monoclonal Antibody Technology, 1984, pp. 1-32).

Brauner-Osborne et al teach the amino acid sequence of GPRCD5 (page 241) which is identical to the instant SEQ ID NO:56. Brauner-Osborne et al do not teach a monoclonal antibody which binds to GPRCD5.

Cambell teaches that it is customary for any group working on a macromolecule to both clone the genes encoding said macromolecule and make a monoclonal antibody that binds thereto, sometimes without a clear objective for their application (page 29, lines 7-10 under “Basic Research”).

It would have been prima facie obvious to make a monoclonal antibody to the CPRC5D protein. One of skill in the art would have been motivated to do so in order to further their research on collagens because it is customary to do so, as exemplified by Campbell.

The teachings of Brauner-Osborne et al in view of Campbell also render obvious the specific embodiments of claim 53 because the intended use of the kit “for detecting a hematological malignancy cell” is not given patentable weight. Further the requirement that the kit contain “instructions for use also does not provide patentable weight. Section 2112.01 of the MPEP states:

*Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. In re Ngai, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). See also In re Gulack, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983) (“Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.*

Claim 39 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laabi et al (EMBO, 1992, vol. 11, pp. 3897-3904) in view of Campbell (Monoclonal Antibody Technology, 1984, pp. 1-32).

Laabi et al teach the amino acid sequence of BCMA which is identical to the instant SEQ ID NO:4 (page 3902). Laabi et al do not teach a monoclonal antibody which binds to the BCMA protein.

Cambell teaches that it is customary for any group working on a macromolecule to both clone the genes encoding said macromolecule and make a monoclonal antibody that binds thereto, sometimes without a clear objective for their application (page 29, lines 7-10 under “Basic Research”).

It would have been *prima facie* obvious to make a monoclonal antibody to the BCMA protein. One of skill in the art would have been motivated to do so in order to further their research on collagens because it is customary to do so, as exemplified by Campbell.

The teachings of Laabi et al in view of Campbell also render obvious the specific embodiments of claim 52 because the intended use of the kit "for detecting a hematological malignancy cell" is not given patentable weight. Further the requirement that the kit contain "instructions for use" also does not provide patentable weight. Section 2112.01 of the MPEP states:

*Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. In re Ngai, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). See also In re Gulack, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983) ("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.*

Claims 34, 35, 38-40, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claudio et al (Blood, September 15, 2002, Vol. 100, pp. 2175-2186) in view of Campbell (Monoclonal Antibody Technology, 1984, pp. 1-32).

Claim 35 is drawn to a method comprising contacting a biological sample from a patient with a monoclonal antibody that specifically binds to SEQ ID NO:56 and detecting the binding of said monoclonal antibody to SEQ ID NO:56. Claim 38 specifies that the malignancy is multiple myeloma,

Claim 40 is drawn to an isolated monoclonal antibody that specifically binds to a polypeptide of SEQ ID NO: 56. The instant specification discloses that SEQ ID NO:56 is Ly1891P which is GPRC5D (page 170).

Claudio et al teach that the nucleic acids encoding both BCMA and GPRCD5 are differentially expressed in multiple myeloma cells taken from patients (page 2178).

Cambell teaches that it is customary for any group working on a macromolecule to both clone the genes encoding said macromolecule and make a monoclonal antibody that binds thereto, sometimes without a clear objective for their application (page 29, lines 7-10 under “Basic Research”).

It would have been prima facie obvious to make a monoclonal antibody to the CPRC5D protein and BCMA protein. One of skill in the art would have been motivated to do so in order to further their research on collagens because it is customary to do so, as exemplified by Campbell. It would have been further obvious to use said monoclonal antibody in an assay with the multiple myeloma cells taken from patients to determine if the elevated level of nucleic acid encoding the GPRCD5 and BCMA proteins was reflected in an elevated level of translated protein.

Further, the teachings of Claudio et al in view of Campbell also render obvious the specific embodiments of claims 52 and 53 because the intended use of the kit "for detecting a hematological malignancy cell" is not given patentable weight. Further the requirement that the kit contain "instructions for use" also does not provide patentable weight. Section 2112.01 of the MPEP states:

*Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. In re Ngai, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). See also In re Gulack, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983) ("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.*

### ***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/  
Primary Examiner, Art Unit 1643